Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/566,350	TATEISHI ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 July 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-9, 11 and 13-20*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611

Applicants arguments filed 07/03/2008 regarding the rejection of claims 1-9, 11 and 13-20 made by the Examiner under 35 USC 103(a) are maintained for the reasons of record in the office actions mailed on 12/11/2007 and 04/10/2008.
In regards to the 103(a) rejection Applicant asserts the following:
A) Modiamo does not teach a penetration rate of bisoprolol of 3-300 ug/hr.cm2; and
B) Example 2 of Hirano does not have a carboxyl group.
With respect to assertion A, the Examiner acknowledges that Modiamo does not teach a rate of bisoprolol penetration which encompassess the instantly claimed range of 3-300 ug/hr.cm2. However, Modiamo does remedy this deficiency by stating that the rate of transdermal pentration can be enhanced by including transdermal absorption enhancers. Modiamo even cites Walters which lists known transdermal enhancers. Moreover, the teachings of Hirano and Higo incorporate transdermal penetration enhancers into their patch formulations. It is taught by Higo that these enhancers are useful because they promote the transdermal deliery of active agents that possess a low diffusion constant for crossing the epidermal barrier. It would have been obvious to one of ordinary skill in the art to include such absorption enhancers with a reasonable expectation for success in increasing the rate of bisoprolol across the skin, resulting in a higher plasma concentration and improved pharmacological action. Applicants arguments are not found persuasive.
With respect to assertion B, the Examiner agrees that Example 2 of Hirano does not include a carboxyl group. It should be noted however that Example 2 was said to be similar, not identical to the instant claims. Hirano as noted in previous office actions is directed to percutaneous treatment devices which are copolymers comprising pressure sensitive adhesives containing methacrylic acid alkyl ester monomers and carboxyilic acid monomers such as acrylic acid and methacrylic acid (see column 6, lines 47-51). However, Hirano disclose multiple pressure sensitive adhesive formulations some of which utilize 2-ethylhexyl acrylate and vinyl acetate and other use 2-ethylhexyl acrylate and meth acrylic acid, see in particular Examples 1 and 7. A person of ordinary skill in the art would be capable of looking at the examples and combine them to arrive at an acrylic adhesive consists of 2-ethylhexyl acrylate, vinyl acetate and methacrylic acid. Applicants arguments are not found persuasive.